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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,989	10/25/2005	Heli Valtanen	0933-0238PUS1	6375

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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05/01/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,989	<b>Applicant(s)</b> VALTANEN ET AL.	
	<b>Examiner</b> MAURY AUDET	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2-18 and 21-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The present application has been transferred from former Examiner Young to the present Examiner.

#### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 13-18, in the reply filed on 3/7/07 is acknowledged. The traversal is on the ground(s) that at least Groups I-II should be examined, if not Groups I-IV. This traversal is deemed moot, in the sense that the election is based on linking claim practice and that ALL groups will be rejoined upon the finding of allowability of linking claim 1 (pursuant to the amendment of the remaining claims commensurate in scope therewith).

Applicant's election of the compound of SEQ ID NO: 24, as the compound of the invention is also acknowledged. Applicant argues this is improper because the main claim [claim 1] is a method. This is not an argument without merit. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Notwithstanding, this Examiner has rejoined SEQ ID NO: 20, with elected SEQ ID NO: 24.

The requirement is still deemed proper and is therefore made FINAL.

Claim 1, the linking claim, is the only claim under examination, as drawn to either SEQ ID NO: 20 or SEQ ID NO: 24.

Claims 19-20 are allowable products not reasonably taught or suggested by the prior art of record.

Claims 2-18 and 21-23 are withdrawn from consideration, as non-elected claims, until the allowability of the linking claim is found.

### ***Claim Objections***

Claims 1 is objected to because of the following informalities: the claims have not been amended commensurate in scope with the elected invention, namely compounds of SEQ ID NOS: 20 and 24. Were the claims so amended thereto, the claims would likely receive favorable consideration. [It is suggested that claims 2-18 and 21-23 also be amended likewise].

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Namely, based on the 7 nucleic acids described within the sequence list, it is unclear which if any is the nucleic acid which is meets the limitation for producing either elected SEQ ID NO: 24 or rejoined SEQ ID NO: 20, as the nucleic acid of step 1:

- providing a nucleic acid molecule encoding a polypeptide comprising a peptide of interest.

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Applicant must amend the claim, if possible based on the description, to distinctly claim that nucleic acid(s) which carry out the making of the peptides above (as well as distinctly claim the elected/rejoined peptides of SEQ ID NO: 24/20).

ALTERNATIVELY:

Claim 1 is also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step(s)/gap arises by the fact that the Examiner cannot ascertain how the following modified elected compound of SEQ ID NO: 24 (modifying core CTT peptide of SEQ ID NO: 10 by adding 6 hydrophobic amino acids to N-terminus), and rejoined SEQ ID NO: 20 (modifying core CTT peptide of SEQ ID NO: 10 at position 5, by adding any of the following three tryptophan analogues: 5-OH-Trp, 5-F-Trp, or 6-F-Trp), can be produced simply via the 4 steps of claim 1:

1. (Original) A method for producing a peptide having at least one disulfide bridge, comprising the steps of

- providing a nucleic acid molecule encoding a polypeptide comprising a peptide of interest,
- incorporating said nucleic acid molecule into an expression vector as a fusion with an intein,
- expressing the peptide-intein-fusion, and
- inducing the peptide cleavage by temperature and pH change.

The omitted step(s) is deemed to constitute one or more steps wherein the skilled artisan must operably modify the peptides of SEQ ID NO: 24 and SEQ ID NO: 20, AFTER the original CTT

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peptide of SEQ ID NO: 10 is made by e.g. the nucleic acid of SEQ ID NO: 3, possibly along with SEQ ID NOS: 4-5? (see sequence listing description) [unless there is description for the nucleic acid capable of producing the above peptides, as discussed in the 1st 112 2nd alternative rejection].

### *Conclusion*

Claims 19-20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 4/20/08

/Maury Audet/

Examiner, Art Unit 1654